K072741

510(k) Summary
Pre~Va Vaginal Lubricant

JUL 16 2008

I. General Information on Submitter

Address:	INGfertility, LLC (Subsidiary of Bio-Origyn, LLC) 17206 S. Spangle Creek Rd. Valleyford, WA 99036 USA
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Contact Person:	G. Dennis Clifton, Pharm.D.
Date Prepared:	March 18, 2008

II. General Information on Device

Proprietary Name:	Pre~Va Vaginal Lubricant
Classification Name:	lubricant, patient, vaginal, latex compatible (21 CFR 884.5300, Product Code NUC)

III. Predicate Devices

Predicate Device	510(k) control #
Pre' Vaginal Lubricant	K051436

IV. Description of Device

This product is a non-sterile, water-based personal lubricant formulated to supplement the body's own natural lubricating fluids. Pre~Va is used to lubricate vaginal tissues to facilitate entry of diagnostic or therapeutic devices including those used in fertility interventions. It is also used as a personal lubricant to supplement the body's own natural lubricating fluids and to enhance the comfort of intimate sexual activity. The formulation does not harm sperm function and has a pH and osmolarity that are physiologic ("balanced") to that of fertile cervical mucus and semen. The product is compatible with latex and polyurethane condoms. Following is the ingredient list for Pre~Va Vaginal Lubricant:

Ingredients
Water
Hydroxyethylcellulose, NF
Pluronic 127, NF
Sodium Chloride, USP
Arabinogalactan
Sodium Phosphate
Carbopol 934P, NF
Methyl Paraben, USP
Sodium Hydroxide, NF
Potassium Phosphate

V. Intended Use

- To lubricate vaginal tissues to facilitate entry of diagnostic or therapeutic devices including those used in fertility interventions. Pre~Va may be applied directly to the device or may be deposited intravaginally using the applicator, prior to the insertion of diagnostic or therapeutic devices used in fertility interventions
- As a personal lubricant Pre~Va supplements the body's own natural lubricating fluids, to moisturize, relieve friction and to enhance the ease and comfort of intimate sexual activity. Pre~Va is safe for use by couples who are trying to conceive and may be applied to vaginal or penile tissues for lubrication and moisturization purposes. It is compatible with latex and polyurethane condoms.

VI. Technological Characteristics of Device Compared to Predicate Device
All of the technological characteristics of Pre~Va are identical to the predicate device.

VII. Summary of Performance Data
The performance data of Pre~Va are identical to the predicate.

VIII. Conclusion
Pre~Va Vaginal Lubricant is safe for its intended use and substantially equivalent to the predicate device Pre' Vaginal Lubricant.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

February 27, 2014

INGfertility, LLC
Dennis Clifton, Pharm.D.
Vice President
17206 South Spangle Creek Road
Valleyford, WA 99036

Re: K072741
Trade/Device Name: Pre-Va Vaginal Lubricant
Regulation Number: 21 CFR§ 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: PEB
Dated (Date on orig SE ltr): July 1, 2008
Received (Date on orig SE ltr): July 8, 2008

Dear Dennis Clifton,

This letter corrects our substantially equivalent letter of July 16, 2008.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner -S

for
Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K072741

Device Name: Pre~Va Vaginal Lubricant

Indications for Use:

- To lubricate vaginal tissues to facilitate entry of diagnostic or therapeutic devices including those used in fertility interventions. Pre~Va may be applied directly to the device or may be deposited intravaginally using the applicator, prior to the insertion of diagnostic or therapeutic devices used in fertility interventions.
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Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use __X____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K072741